DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

91385d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

June 14, 2001

Marvin Weiner, M.D.
Medical Director of Radiology
A N T Imaging Center
14044 Victory Boulevard
Van Nuys, CA 91401

W/L Number: 56 - 01
Inspection ID: 2109300006
CFN: 20-30,719
FEI: 3000204005

Dear Dr. Weiner:

We are writing to you because on May 31, 2001, your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

- Level 1: Processor quality control (QC) records in the month of January 2001 were missing for at least 30% of operating days and were out of limits on at least five (5) days for processor #1 (a [redacted] machine, style [redacted], model [redacted] or [redacted]) which is located in the darkroom.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further

notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: Processor QC records were missing at least two (2) but less than five (5) consecutive days for processor #1 (a [redacted] machine, style [redacted], model [redacted] or [redacted]) which is located in the darkroom.

- Level 2: There were no examples of, nor attempts, to get biopsy results.

- Level 2: Corrective actions for processor QC failures were not documented at least once for processor #1 (a [redacted] machine, style [redacted], model [redacted] or [redacted]) which is located in the darkroom.

- Level 2: The facility has not specified adequate procedures to be followed for infection control or did not follow them when required.

- Level 2: Medical audit and outcome analysis was not performed annually.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations; and

- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

re: A N T Imaging Center
re: Warning Letter Number 56 - 01

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (telephone number 1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number 949-798-7708.

Sincerely,

Alonza E. Cruse
District Director

cc:

State of California
Dept. of Health Services
Radiological Health Unit
550 South Vermont Avenue; Suite #601
Los Angeles, CA 90020